UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

PDL BioPharma, Inc., Plaintiff, v. Eli Lilly and Company, Defendant.	Civil Action No.1:23-cv-02289-RLY-MKK

PDL BIOPHARMA, INC.'S RESPONSIVE BRIEF IN OPPOSITION TO ELI LILLY AND COMPANY'S MOTION TO DISMISS UNDER RULES 12(b)(1) AND 12(b)(6)

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

Defendant Eli Lilly & Company's motion to dismiss is an exercise in exaggeration. Lilly ***understates*** the factual allegations in Plaintiff PDL Biopharma, Inc.'s complaint when arguing that it fails to meet the notice pleading standard. In fact, the complaint clearly specifies the provisions of the parties' agreement that Lilly has unequivocally refused to perform and the reasons that Lilly will be obligated to perform upon FDA approval of donanemab. At the same time, Lilly ***overstates*** the caselaw underpinning its motion when arguing that it has proffered a good-faith interpretation of the contract that precludes repudiation (it has not), that the Declaratory Judgment Act is exclusively reserved for "natural defendants" (it is not), and that the complaint fails to allege an immediate and concrete dispute between the parties (it does). A fair reading of the complaint, in light of the applicable case law, reveals that it is factually and legally sufficient in all respects. Lilly's motion should be denied.

First, the complaint includes detailed factual allegations that donanemab is a "Licensed Product" as that term is defined in the parties' Development and License Agreement, dated September 15, 2000 (the "Agreement"). Lilly attempts to sidestep these factual allegations by characterizing them as legal conclusions. But framing factual allegations with reference to the contractual definition of "Licensed Product" in the Agreement does not transform them into legal conclusions. The complaint's factual allegations are more than sufficient to satisfy the notice pleading standard.

Second, Lilly misconstrues the law to demand dismissal of PDL's anticipatory breach of contract and declaratory judgment claims. As to PDL's anticipatory breach of contract claim, Lilly argues that there can be no anticipatory breach because it has proffered a good-faith interpretation of the contract. But PDL does not plead that Lilly has proffered a "good-faith" interpretation; rather, PDL alleges that Lilly has unequivocally refused to comply with its obligations under the

agreement. Lilly's contention that there can be no anticipatory breach because it has relied on a good-faith interpretation of the Agreement merely raises a factual dispute that cannot be resolved on a motion to dismiss. As to PDL's declaratory judgment claim, Lilly argues that PDL is barred from bringing its claim because the Declaratory Judgment Act is reserved exclusively for "natural defendants" and cannot be invoked by a natural plaintiff such as PDL. But there is no *per se* prohibition against a natural plaintiff bringing a declaratory judgment claim, as evidenced by the many cases affirming the right of a patentee (a natural plaintiff) to bring a declaratory judgment action in advance of actual infringement by an accused infringer (a natural defendant). In fact, as a dissolved corporation, PDL uniquely requires the Court's intervention so it can understand whether it will be owed royalties and thus must seek continuation of its corporate existence for the duration of the royalty term under the Agreement.

Third, Lilly overstates the law to argue that PDL lacks standing because the FDA has not yet approved donanemab. Yet, many cases have held that FDA approval is not required to bring a declaratory judgment claim, so long as the dispute is immediate and concrete. It is enough that, as the complaint pleads, Lilly has broadcasted its expectation that FDA approval and, as a result, harm to PDL, will occur imminently.

I. BACKGROUND

A. PDL Invented a New Method to Humanize Antibodies

Antibodies are a part of the immune system that bind to foreign substances, called antigens. ECF No. 1 (Complaint for Anticipatory Breach of Contract and Declaratory Judgment) ¶ 8. An antibody is a Y-shaped protein that consists of two identical heavy chains and two identical light chains. *Id.* ¶ 9. Each chain (heavy or light) is divided into a variable region, which binds to a particular antigen, and a constant region, which activates other immune system components to destroy the bound antigen. *Id.* ¶ 10.

Scientists seeking to develop an antibody to target a specific antigen associated with a human disease typically begin by producing the desired antibody in an animal such as a mouse. *Id.* ¶ 12. But animal antibodies are immunogenic in humans. *Id.* ¶ 13. In other words, the human body will recognize an animal antibody as foreign and mount an immune response against the animal antibody, instead of using the animal antibody to mount an immune response against the target antigen. *Id.* To solve this problem, scientists developed techniques to "humanize" animal antibodies (i.e., to make changes to the animal antibody such that the human body recognizes the antibody as native instead of foreign). *Id.* ¶¶ 14-16. These solutions were met with mixed results: some resulted in a humanized antibody that was still immunogenic, while other resulted in a humanized antibody with lost affinity for (i.e., that binds less tightly to) the target antigen. *Id.*

PDL scientists invented a new method for humanizing antibodies. *Id.* ¶ 17. This method resulted in antibodies that are substantially non-immunogenic yet also retain high affinity for the target antigen. *Id.* PDL has broad intellectual property covering its humanization technology, including foundational patents and considerable know-how. *Id.* ¶ 18. PDL broadly licensed its intellectual property rights to pharmaceutical and biotechnology companies, including Lilly. *Id.* ¶ 19.

B. PDL Licensed Its Intellectual Property Rights to Lilly

In 2000, PDL and Lilly entered into the Agreement, by which PDL used its humanization technology to humanize at least three antibodies directed against the human beta-amyloid antigen for Lilly (referred to as the "Humanized Antibodies" in the Agreement). *Id.* ¶¶ 20-21. Beta-amyloid is a protein that accumulates to form plaque found in the brain of patients with Alzheimer's Disease. *Id.* ¶ 20. PDL also granted Lilly a license to its intellectual property (including patents, know-how, and other technical information) in exchange for royalty payments on any "Licensed Product." *Id.* ¶ 22. The Agreement defined "Licensed Product" to be broader

than just the "Humanized Antibodies"—specifically, "Licensed Product" means "a pharmaceutical product that incorporates ***substantially all of at least one (1) variable region*** of the Humanized Antibody(ies) developed by PDL under this Agreement." *Id.* ¶ 23 (quoting Agreement § 1.11) (emphasis added). In other words, a "Licensed Product" need not be an antibody humanized by PDL for Lilly but can also be an antibody humanized by Lilly that incorporates substantially all of at least one variable region of an anti-beta-amyloid antibody humanized by PDL under the Agreement. *See id.*

As amended in 2009, the Agreement obligates Lilly to pay a royalty on sales of Licensed Products that "incorporate[] the PDL Technical Information." *Id.* ¶ 25 (quoting Amendment § 2(a)(1)). "PDL Technical Information" is broadly defined as "any and all inventions, discoveries, know-how, trade secrets, information, experience, technical data, formulas, procedures, results or materials (including any biological materials and samples) which are rightfully held by PDL and which technical information is necessary for the research, development, registration, manufacture, use or sale of the Humanized Antibody." *Id.* ¶ 24 (quoting Agreement § 1.20).

C. Lilly Developed Donanemab, an Antibody That Falls Within the Scope of the Agreement and Will Be Approved by the FDA Imminently

Lilly humanized donanemab, an antibody that targets the same beta-amyloid antigen as the PDL-humanized antibodies. *Id.* ¶ 27. As pled, donanemab is a "Licensed Product" that incorporates "PDL Technical Information." *Id.* ¶¶ 28-30. As a result, Lilly will soon owe PDL royalties on sales of donanemab. *Id.* ¶ 31.

Lilly will owe royalties on donanemab "within sixty (60) days after the close of each Calendar Quarter during the term of this Agreement, beginning with the Calendar Quarter in which the date of First Commercial Sale following regulatory approval occurs." *Id.* ¶ 37 (quoting Agreement § 4.09). Such approval is imminent. Lilly shared the results of donanemab's Phase III

clinical trial at the 2023 Alzheimer's Association International Conference on July 17, 2023, and simultaneously published those results in the Journal of American Medicine Association. *Id.* ¶ 33. Lilly completed its application to the FDA for donanemab in Q2 2023. *Id.* And at its Q3 2023 Earnings Call, Lilly noted that it expected FDA approval of donanemab for the treatment of Alzheimer's disease in Q1 2024. *Id.*

After PDL filed the Complaint,[1] the FDA convened an advisory committee meeting for donanemab (as it has for prior FDA-approved antibodies for the treatment of Alzheimer's disease). Ex. A.[2] This meeting has delayed approval beyond Q1 2024. *Id.* Nevertheless, Lilly has reiterated its confidence that donanemab will be approved by the FDA. *Id.* ("We are confident in donanemab's potential to offer very meaningful benefits to people with early symptomatic Alzheimer's disease."); Ex. B at 4 (noting that Lilly "remains confident in approval"). Approval is still expected this year. Ex. B at 4 ("continu[ing] to expect an approval for donanemab later this year" based on recent meetings with Lilly's management meetings).

On March 22, 2023, PDL wrote to Lilly, explaining that donanemab is a "Licensed Product" that incorporates "PDL Technical Information" under the Agreement. ECF No. 1 ¶ 31. Lilly disagreed. *Id.* ¶ 32. The parties eventually exchanged multiple letters (in total, six) on the issue but were unable to come to a resolution as to whether donanemab is a "Licensed Product" that incorporates "PDL Technical Information." *Id.* As a result, Lilly has indicated that it does not intend to pay royalties to PDL for donanemab. *Id.* PDL thus filed the instant complaint alleging anticipatory breach of contract and declaratory judgment claims. *Id.* ¶¶ 32, 37, 39-41.

[1] PDL does not rely on events that occurred after the filing of the complaint to establish its standing to sue Lilly. PDL provides this background as additional context for the Court.

[2] Exhibits A and B cited herein are attached to the Declaration of Jordan B. Fernandes, filed herewith.

D. PDL Is a Dissolved Delaware Corporation

PDL dissolved on January 4, 2021. *Id.* ¶ 3. Under Delaware law, a dissolved corporation continues its corporate existence for at least three years from dissolution—here, until January 4, 2024—and, at the discretion of the Delaware Court of Chancery, can continue its corporate existence beyond the three-year period, including to prosecute claims (as PDL seeks to do here). *Id.* PDL has already received permission from the Delaware Court of Chancery to continue its corporate existence until October 24, 2024. *Id.* And PDL can and will seek further continuation of its corporate existence until resolution of this lawsuit. *Id.* With respect to the instant suit, PDL "shall 'be continued as a body corporate beyond the 3-year period and until any judgments, orders or decrees therein shall be fully executed, without the necessity for any special direction to that effect by the Court of Chancery.'" *Id.* (quoting 8 Del. Code § 278).

II. ARGUMENT

A. The Complaint Satisfies the Notice Pleading Standard by Providing Specific Factual Allegations to Support the Legal Claims Contained Therein

Rule 8 requires a complainant to provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). When deciding a motion to dismiss under Rule 12(b)(6), a court must accept all factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007). A Rule 12(b)(6) motion may be granted only if, accepting the well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the plaintiff, the court concludes that those allegations "could not raise a claim of entitlement to relief." *Id.*

Lilly argues that the complaint "falls well short of the pleading standard required under *Twombly* and *Iqbal*." ECF No. 36 (Lilly's Memorandum of Law in Support of Its Motion to Dismiss Under Rules 12(b)(1) and 12(b)(6)) at 6. Specifically, Lilly identifies PDL's factual

allegations regarding whether donanemab is a "Licensed Product" under the Agreement as supposedly warranting dismissal.[3] But despite acknowledging that a plaintiff must only plead facts sufficient to state a claim, Lilly seeks to hold PDL to a higher standard: one where the plaintiff is required to ***prove*** those facts. *Id.* Unsurprisingly, its arguments are without merit.

The complaint claims that "[d]onanemab is a 'Licensed Product' under the Agreement." ECF No. 1 ¶ 28. The complaint then pleads factual allegations to support that claim: "PDL humanized at least three anti-beta-amyloid antibodies for Lilly" and "donanemab incorporates substantially all of the variable light chain region of one or more of the antibodies humanized by PDL for Lilly." *Id.* ¶¶ 21, 28. While Lilly acknowledges that the complaint includes these factual allegations, Lilly nonetheless contends that "PDL does not allege any facts in support of its essential assertion that donanemab is a 'Licensed Product' under the Agreement." ECF No. 36 at 6.

Lilly faults PDL for not "identify[ing] which PDL-humanized antibody donanemab supposedly incorporates [or] how much was incorporated." *Id.* at 7. But this information is contained in the aforementioned factual allegations: the complaint pleads that "PDL humanized at least three anti-beta-amyloid antibodies for Lilly" and that donanemab incorporates "substantially all of the variable light chain region of one or more of the antibodies humanized by PDL for Lilly." ECF No. 1 ¶¶ 21, 28. Lilly asserts that "every antibody has two identical light chains . . . , so shoehorning the phrase 'light chain' into the contractual definition tells the Court nothing further about donanemab's composition or inclusion of a PDL-made antibody." ECF No. 36 at 7. This assertion is inapt at best. As the complaint pleads, "[a]n antibody consists of . . . two identical light

[3] Lilly does not dispute that the complaint alleges sufficient factual allegations that donanemab incorporates "PDL Technical Information" under the Agreement. *See* ECF No. 36 at 8-9.

chains." ECF No. 1 ¶ 9. That means that the two light chains in a specific antibody are identical, not that the two light chains in "every antibody" are identical. *See id.* Indeed, as Lilly admits, the light chains in one antibody are expected to vary from the light chains in another antibody. ECF No. 36 at 3 (explaining that "light chains" are "comprised of a constant region (which is similar across all antibodies) and a variable region (that varies across all antibodies)"). The complaint puts Lilly on notice that donanemab "incorporates substantially all of the variable light chain region" of at least one antibody that PDL humanized for Lilly—in other words, the donanemab light chain is substantially similar to the light chains of at least one PDL-humanized antibody—and is thus a "Licensed Product." *Id.* ¶ 28.

Lilly also faults PDL for not explaining "what Lilly supposedly did to incorporate substantially all of that antibody into donanemab." ECF No. 36 at 7. But the relevant inquiry is simply whether donanemab incorporates "substantially all of at least one (1) variable region" of an antibody that PDL humanized for Lilly. ECF No. 1 ¶ 23. Nothing in the Agreement requires that the incorporation be accomplished in a particular manner. *See id.* Lilly also chides PDL for not including factual allegations "plausibly showing that a PDL-made antibody is part of . . . donanemab." ECF No. 36 at 7. But, again, nothing in the contractual definition of "Licensed Product" requires that donanemab incorporate part of a PDL-made antibody. *See* ECF No. 1 ¶ 23 (discussing the contractual definition of "Licensed Product"). PDL has pled that Lilly "incorporate[d] substantially all of the variable light chain region of one or more of the antibodies humanized by PDL for Lilly" into donanemab. *Id.* ¶ 28. That is more than sufficient to plausibly allege that donanemab is a Licensed Product.

Lilly attempts to recast PDL's factual allegations as "a thinly dressed-up legal conclusion" because it "parrots the contractual definition of 'Licensed Product.'" ECF No. 36 at 6-7. Lilly's

argument is nonsensical—a factual allegation supporting that donanemab is a "Licensed Product" is, of course, framed around the contractual definition of that term. Lilly ***never*** disputes that if "donanemab incorporates substantially all of the variable light chain region of one or more of the antibodies humanized by PDL for Lilly" (as the complaint pleads), then donanemab is a "Licensed Product." This is all that is required. *Chapman v. Yellow Cab Cooperative*, 875 F.3d 846, 848 (7th Cir. 2017) ("It is enough to plead a plausible claim, after which 'a plaintiff receives the benefit of imagination, so long as the hypotheses are consistent with the complaint.'") (quoting *Twombly*, 550 U.S. at 563). Further detail will be the subject of fact and expert discovery. *Id.* ("A full description of the facts that will prove the plaintiff's claim comes later, at the summary-judgment stage or in the pretrial order."); *see also Smith v. Golden Rule Ins. Co.*, 526 F. Supp. 3d 374, 390 (S.D. Ind. 2021) ("further discovery and potentially expert testimony will be required to prove or disprove [the pled claim]"). For example, PDL will seek and offer discovery regarding the meaning of "incorporate substantially all" and will seek discovery regarding the design and development of donanemab. And PDL will proffer expert discovery regarding comparisons of donanemab and the antibodies that PDL humanized for Lilly.

The caselaw relied upon by Lilly is inapposite. Lilly cherry-picks extreme cases where the plaintiff proffered woefully insufficient pleadings. The only relevance to PDL's complaint is that these cases concern the same type of claims as those asserted here (i.e., claims related to a breach of contract). For example, Lilly attempts to draw parallels to *Defender Security Co. v. First Mercury Insurance Co.*, 803 F.3d 327 (7th Cir. 2015). ECF No. 36 at 7. In *Defender Security*, the Seventh Circuit reasoned that "[i]f, to establish coverage under the Policy, Defender eventually needed to prove that publication occurred, it should have pled sufficient facts to make that showing, or elaborated in its opposition brief on the facts it intended to prove." 803 F.3d at 335.

Since "Defender did neither," the Seventh Circuit affirmed dismissal of the complaint. *Id.* In contrast, PDL's complaint affirmatively pleads sufficient facts, as detailed and explained above, to show that donanemab is a "Licensed Product." *See id.*

Lilly also attempts to draw parallels to *Huo v. Synchrony Bank*, No. 19-cv-03881, 2020 WL 2128729 (N.D. Ill. May 5, 2020), arguing that PDL's complaint "merely identifies a relevant provision and alleges Lilly breached it with no effort to 'allege why' or 'detail' how donanemab meets the relevant definition." ECF No. 36 at 7. In *Huo*, the court dismissed a breach of contract claim, reasoning that "[i]f this Court requires Huo to identify the provision of the contract Synchrony allegedly breached, then the pleading is clearly insufficient." 2020 WL 2128729, at *3. In contrast, the complaint here identifies the specific provisions of the Agreement that will be breached and detailed factual allegations for why a breach will occur. ECF No. 1 ¶ 37.

Lilly also cites to *Bissessur v. Indiana University Board of Trustees*, 581 F.3d 599 (7th Cir. 2009), but that case, too, is irrelevant. ECF No. 36 at 7-8. In that case, the plaintiff (Bissessur) alleged that he entered into an implied contract with a university but did not plead any facts "concerning: (1) what, if any, promises the University made to Bissessur; (2) how these promises were communicated; (3) what Bissessur promised in return; or (4) how these promises created an implied contract." *Bissessur*, 581 F.3d at 603-04. The Seventh Circuit explained that "[a] plaintiff may not escape dismissal on a contract claim, for example, by stating that he had a contract with the defendant, gave the defendant consideration, and the defendant breached the contract." *Id.* at 603. And the Seventh Circuit concluded that the complaint "leaves the University with no notice of what this 'implied cont[r]act' is or how it supports Bissessur's constitutional claims." *Id.* at 604. In contrast, PDL's complaint pleads that "PDL and Lilly initially entered into a Development and License Agreement" and attaches that agreement as Exhibit 1. ECF No. 1 ¶ 21. The complaint also

pleads relevant details of the Agreement (*id.* ¶¶ 22-25), why PDL is entitled to royalties for donanemab (*id.* ¶¶ 28-30), and how Lilly has anticipatorily breached (and will actually breach) the Agreement (*id.* ¶ 37).

In sum, the complaint pleads sufficient factual allegations to state a claim. The factual allegations explain not only that donanemab ***is*** a "Licensed Product" but also ***why*** donanemab is a "Licensed Product." The complaint further alleges that, even though donanemab incorporates PDL Technical Information, Lilly has unequivocally refused to pay royalties to PDL on donanemab once it is commercialized after FDA approval. *Id.* ¶¶ 31-32, 37. This is more than enough to satisfy the notice pleading standard.

B. PDL's Claims Are Warranted Under the Law Governing Anticipatory Breach of Contract and Declaratory Judgment Claims

The complaint alleges both anticipatory breach of contract and declaratory judgment claims. Lilly argues that both claims should be dismissed as a matter of law because (1) Lilly has not repudiated the Agreement since it has purportedly offered to perform consistent with a good-faith interpretation of the Agreement, and (2) PDL is prohibited from pursuing declaratory judgment claims against Lilly because it would not be a natural defendant in a breach of contract claim. But Lilly incorrectly interprets and applies the law to the facts pled in the complaint.

1. PDL's Complaint Adequately Alleges that Lilly Has Repudiated Its Contractual Obligations

Count I of the complaint is an anticipatory breach of contract claim. Under California law, "an anticipatory breach of contract occurs when the contract is repudiated by the promisor before the promisor's performance under the contract is due." *Central Valley General Hospital v. Smith,* 162 Cal. App. 4th 501, 514 (2008). The complaint pleads specific facts evidencing Lilly's express repudiation of the Agreement. First, the complaint chronicles the parties' correspondence regarding the Agreement. ECF No. 1 ¶¶ 31-32. Then, the complaint pleads that "Lilly

unequivocally stated that donanemab is not a 'Licensed Product' and that it does not incorporate 'PDL Technical information'" and that "Lilly also unequivocally stated that it will not pay royalties to PDL on sales of donanemab." *Id.* ¶ 37. In light of these unequivocal statements, the complaint alleges that "Lilly has expressly repudiated the Agreement and anticipatorily breached Section 4.09 of the Agreement" and "has also expressly repudiated the Agreement and anticipatorily breached Section 4.10 of the Agreement." *Id.*

Lilly argues that PDL's anticipatory breach of contract claim should be dismissed because "[n]othing in the complaint plausibly suggests Lilly unequivocally repudiated an obligation under the Agreement." ECF No. 36 at 11. As detailed above, that is ***exactly*** what PDL alleges. The complaint pleads that Lilly has clearly, positively, and unequivocally informed PDL that it will not pay royalties on donanemab and will thus refuse to perform under the Agreement. ECF No. 1 ¶ 37.

Lilly contends that "when there is a disagreement as to the meaning of the terms in a contract, one party's offer to perform in accordance with his interpretation is not itself an anticipatory breach." *Pacific Coast Eng'g Co. v. Merritt-Chapman & Scott Corp.*, 411 F.2d 889, 894 (9th Cir. 1969). But Lilly is not offering to perform. *See id.* at 896 (finding repudiation where the party "persistently demanded an unwarranted condition precedent to its required performance"). Rather, as explained in Lilly's motion, Lilly contends it has no further obligation to perform because "none of the PDL-humanized antibodies ever became 'Licensed Products' under the Agreement." ECF No. 36 at 4. In other words, Lilly's supposed interpretation forecloses Lilly from ever having to perform under the Agreement again.

Moreover, it is well-settled California law that "[i]f the offeror is not asserting a good faith interpretation of the contract terms, that fact may be evidence that he is repudiating the agreement."

Pacific Coast Eng'g, 411 F.2d at 895. Lilly simply presumes that it has proffered a "good-faith disagreement." ECF No. 36 at 9 ("Lilly's good-faith disagreement about the application of disputed contractual provisions does not constitute an anticipatory breach"). But the complaint does not plead, and PDL does not agree, that Lilly has proffered a good-faith interpretation of the contract terms.

Based on its pre-suit correspondence, Lilly appears to rely on an interpretation of the contract that limits the scope of the Agreement to the specific antibodies that PDL humanized for Lilly. *See* ECF No. 1 ¶ 40 ("Lilly has stated that donanemab does not incorporate 'PDL Technical Information' with reference to Example 1 of the '498 patent and because PDL had ***no role*** in the humanization of donanemab") (emphasis added). That interpretation would rewrite the contractual definition of "Licensed Product" to be "a pharmaceutical product that incorporates ~~substantially all of at least one (1) variable region of~~ the Humanized Antibody(ies) developed by PDL under this Agreement." *See* Agreement § 1.11. And it would render meaningless the requirement that the Licensed Product "incorporate PDL Technical Information" since any antibody humanized by PDL will necessarily incorporate PDL Technical Information. *See* Amendment § 2(a)(1). Lilly's position, on its face, does not represent a good-faith interpretation of the Agreement. *Zalkind v. Ceradyne, Inc.*, 194 Cal. App. 4th 1010, 1027 (2011) ("To the extent practicable, the meaning of a contract must be derived from reading the whole of the contract, with individual provisions interpreted together, in order to give effect to all provisions and to avoid rendering some meaningless."). Lilly's argument to the contrary simply raises a factual dispute that cannot be resolved on a motion to dismiss under Rule 12(b)(6). *See Manning v. Sweitzer*, 891 F. Supp. 2d 961, 967-68 (N.D. Ill. 2012) (denying motion to dismiss due to factual disputes that "cannot be answered at this stage of the case").

2. <u>There Is No *Per Se* Prohibition Against a Natural Plaintiff Bringing a Declaratory Judgment Claim</u>

Count II of the complaint is a declaratory judgment claim. PDL seeks (1) "a declaratory judgment that donanemab is a 'Licensed Product' under the Agreement," (2) "a declaratory judgment that donanemab incorporates 'PDL Technical Information' as defined in the Agreement," and (3) "a declaratory judgment that a royalty is owed to PDL for donanemab under the terms of the Amendment." ECF No. 1 ¶¶ 39-41. This is the type of dispute that the Declaratory Judgment Act was intended to address. *Hardware Mutual Casualty Co. v. Schantz*, 178 F.2d 779, 780 (5th Cir.1949) ("The purpose of the Declaratory Judgment Act is to settle 'actual controversies' before they ripen into violations of law or a breach of some contractual duty.")

Lilly argues that PDL's declaratory judgment claim should be dismissed because "it does not meet the requirements of the Declaratory Judgment Act." ECF No. 36 at 11. Specifically, according to Lilly, "[t]he Act is ***reserved*** for 'natural defendants' who want to take a course of conduct but are uncertain of whether that conduct will subject them to liability in a future lawsuit." *Id.* (emphasis added). Contrary to Lilly's argument, natural plaintiffs (such as PDL) routinely bring declaratory judgment claims. *See, e.g., Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997) ("A patentee may seek a declaration that a person will infringe a patent in the future."); *Lang v. Pacific Marine and Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990) ("If the controversy requirement is met by a sufficient allegation of immediacy and reality, we see no reason why a patentee should be unable to seek a declaration of infringement against a future infringer when a future infringer is able to maintain a declaratory judgment action for noninfringement under the same circumstances.").

None of the cases cited by Lilly supports a *per se* prohibition on declaratory judgment claims initiated by natural plaintiffs or a *per se* reservation of such claims for natural defendants.

In *Medical Assurance Co. v. Hellman*, the Seventh Circuit explained that "[t]he goal of the Declaratory Judgment Act is to allow for the efficient resolution of disputes by an early adjudication of the rights of the parties." 610 F.3d 371, 377 (7th Cir. 2010). That is precisely what PDL seeks here by pursuing a declaratory judgment ***now***. Lilly has already telegraphed its intention to breach the Agreement. ECF No. 1 ¶ 32. A declaratory judgment will allow the Court to efficiently and timely resolve the parties' dispute. There is simply no reason to wait until Lilly actually breaches the Agreement by failing to provide notice of marketing approval within sixty days after FDA approval of donanemab and subsequently failing to pay royalties on net sales of donanemab. *See id.* ¶ 37 (breaching Agreement §§ 4.09, 4.10).

Lilly relies upon a parenthetical quotation in *Medical Assurance* from Wright & Miller, stating that "[t]he remedy made available by the Declaratory Judgment Act . . . relieves potential defendants from the Damoclean threat of impending litigation which a harassing adversary might brandish, while initiating suit at his leisure—or never." 610 F.3d at 377 (alteration in original). Putting aside the implausibility that the Seventh Circuit would announce such a *per se* rule in a parenthetical quotation, this statement merely reflects the reality that many declaratory judgment claims are brought by natural defendants who seek clarity with respect to a proposed future course of action. It does not reflect a *per se* rule that declaratory judgment claims are reserved for natural defendants.

Likewise, in *Maytag Corp. v. International Union, United Automobile, Aerospace & Agricultural Implemental Workers of America*, the Eighth Circuit explained that "[i]n the context of disputes between parties to a contract, the declaratory judgment remedy 'is intended to provide a means of settling an actual controversy before it ripens into a violation of the civil or criminal law, or a breach of a contractual duty.'" 687 F.3d 1076, 1081 (8th Cir. 2012) (quoting *Rowan Cos.*

v. Griffin, 876 F.2d 26, 28 (5th Cir. 1989)). Again, this is precisely what PDL seeks to do here. The Eighth Circuit further explained that "relevant Article III considerations include whether the contractual dispute is real, in the sense that it is not factually hypothetical; whether it can be immediately resolved by a judicial declaration of the parties' contractual rights and duties; and whether 'the declaration of rights is a *bona fide* necessity for the natural defendant/declaratory judgment plaintiff to carry on with its business.'" *Id.* at 1082 (quoting *Hyatt Int'l Corp. v. Coco*, 302 F.3d 707, 712 (7th Cir. 2002)).

Lilly ignores the first two factors—here, the parties clearly have, and the complaint clearly pleads, disputes over the Agreement that could be immediately resolved by judicial declaration. ECF No. 1 ¶¶ 39-41. Moreover, a judicial declaration is a *bona fide* necessity for both parties since it will allow them to understand whether royalties will be paid by Lilly to PDL on sales of donanemab. A judicial declaration is uniquely important to PDL as a dissolved corporation. *See supra* Section I.D. PDL and its shareholders need to know whether royalties will be paid to it, so PDL can take the necessary steps to continue its corporate existence for the duration of the royalty period. *See id.* Since Lilly has unequivocally refused to pay royalties on donanemab once it receives FDA approval, a judicial declaration is the most expeditious mechanism for PDL to obtain a determination of its rights under the Agreement.

Lilly also relies on *Griggers RC Management Holdings, LLC v. Shopf*, which describes a "***usual*** declaratory judgment pattern." No. 1:17-cv-03410-JMS-DML, 2018 WL 1505014, at *9 (S.D. Ind. Mar. 27, 2018). The facts pled by PDL may not fall within this "usual" declaratory judgment fact pattern. But nowhere in *Griggers* does it state that different fact patterns must be dismissed as a matter of law. *See id.* Indeed, other courts have clarified that "the 'usual declaratory

judgment pattern' is ***not a necessary condition*** to the existence of an 'actual controversy.'" *Cohen v. Orthalliance New Image, Inc.*, 252 F. Supp. 2d 761, 767 (N.D. Ind. 2003) (emphasis added).

Lilly also argues that "[c]ourts dismiss declaratory judgment claims under these circumstances" and that "[t]his Court should do the same." ECF No. 36 at 12. Lilly cites a single case in support. *Id.* But this case is readily distinguishable from PDL's declaratory judgment claim. There, the plaintiff sought a declaratory judgment that the parties' contract was unenforceable. *Cohen*, 252 F. Supp. 2d at 766. Since "[u]nenforceability [] is generally a defense to a breach-of-contract action," the court reasoned that this was "generally the type of hypothetical question federal courts endeavor to avoid." *Id.* That is not what PDL asks this Court to do. PDL asks the Court to resolve a dispute as to Lilly's obligations to pay royalties to PDL under the Agreement (i.e., a potential breach of contract claim), not a defense to that claim. Indeed, Lilly admits as much, stating that "[i]f the FDA approves donanemab and Lilly begins commercialization, and then refuses to pay royalties, PDL can then pursue the claims it pursues here by filing a breach-of-contract suit." ECF No. 36 at 12.

C. PDL Has Standing Under the Declaratory Judgment Act

To demonstrate Article III standing, a plaintiff must "suffer[] an 'injury in fact'—an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (internal quotations and citations omitted). The complaint pleads an "injury in fact": PDL will be injured if Lilly does not pay royalties to PDL for donanemab as required by the Agreement. ECF No. 1 ¶¶ 32, 37, 41. Lilly does not dispute that this injury is concrete and particularized but argues that it is not sufficiently actual or imminent. ECF No. 36 at 12-14. The complaint further pleads, however, that Lilly "expected FDA approval of donanemab for the treatment of Alzheimer's disease in Q1 2024." ECF No. 1 ¶ 33.

FDA approval for donanemab did not occur in Q1 2024, as Lilly anticipated.[4] *See supra* Section I.C. But approval is still expected this year. *See id.* Once donanemab is approved by the FDA, Lilly concedes its standing challenge "will be mooted." ECF No. 36 at 13 n.2. Even now, before donanemab is approved by the FDA, Lilly's standing challenge should be rejected. This challenge is just another unwarranted attempt by Lilly to delay the efficient and timely resolution of the parties' dispute.

Lilly argues that "[d]onanemab has not been approved by the FDA," so "PDL's claims depend on contingent future harm." ECF No. 36 at 14. But "[c]laims that FDA approval is required for a district court to rule on a declaratory judgment action have been continually rejected." *Shoulder Innovations v. Ascension Orthopedics, Inc.*, No. 11–810 (JEI/AMD), 2012 WL 2092379, at *3 (D. Del. June 8, 2012). Indeed, courts routinely find that harm is sufficiently imminent even though FDA approval has not yet been received. *See, e.g.*, *Glaxo, Inc.*, 110 F.3d at 1571 (finding "declaratory relief [] available" where "sufficient facts are alleged to create an actual case or controversy" such as "imminent FDA approval"). For example, in *LifeScan Scotland, Ltd. v. Shasta Technologies, LLC*, the court found sufficient immediacy "[a]lthough the date of FDA approval [was] uncertain," because of "statements to the SEC indicat[ing] that that date [would] be imminent." No. 5:11-CV-04494 EJD, 2012 WL 2979028, at *6 (N.D. Cal. July 19, 2012). Similarly, in *Allergan, Inc. v. Revance Therapeutics, Inc.*, the court found sufficient immediacy due, in part, to "public statements that it anticipated FDA approval in 2021." No. 21-1411-RGA, 2022 WL 2866723, at *5 (D. Del. July 21, 2022), *report and recommendation adopted*, Oral Order,

[4] The parties have agreed to a short stay of discovery until (1) donanemab receives FDA approval or (2) the Court denies Lilly's motion to dismiss. ECF No. 39 at 4. This agreement simply reflects that this Court typically sets a quick schedule. It does not mean that PDL lacks standing prior to FDA approval or that PDL does not believe that approval is imminent.

ECF No. 44 (August 19, 2022). So too here. The date of FDA approval for donanemab may have now been delayed, but as pled, Lilly has made public statements, including to investors, that it expects FDA approval imminently. ECF No. 1 ¶ 33.

Lilly relies on two cases to argue that "[o]ther courts have [] held claims alleging that a defendant 'expects' FDA approval are not sufficiently immediate to be justiciable." ECF No. 36 at 14. Both cases are readily distinguishable from this case. In *Clarus Therapeutics, Inc. v. Lipocine, Inc.*, the court found that "[i]mmediacy was [] lacking at the time the complaint was filed and is still lacking, almost a year later, as there is no indication that either FDA approval or Defendant's entry into the market is imminent." No. 15-1004-RGA-MPT, 2016 WL 5868065, at *3 (D. Del. Oct. 6, 2016). Unlike in *Clarus*, Lilly has made affirmative statements about its expectation for donanemab to be approved. *See* ECF No. 1 ¶ 33. There is thus an "indication" that FDA approval is imminent. Indeed, the court in *Allergan* distinguished *Clarus*, explaining that "[t]he facts [in this case] permit a reasonable inference that FDA approval was imminent." 2022 WL 2866723, at *5 (alteration in original). In *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, the court found "no controversy of sufficient immediacy" even though FDA approval was expected within nine months because there was no certainty that the approved device "would be the same as the device that began clinical trials." No. 05-590 GMS, 2006 WL 2375035, at *3 (D. Del. Aug. 16, 2006). But *Abbott* concerned a medical device, and medical devices can change during the course of clinical trials. *Id.* Biologics, such as donanemab, cannot be changed pending FDA approval without submitting an entirely new Biologics License Application to the FDA.

Lilly also argues that "[c]ontingent harms are not actionable." ECF No. 36 at 13. But none of the cases relied upon by Lilly supports such a categorical rule. Instead, they reflect a body of caselaw where the injury was so speculative that judicial resolution was premature. For example,

in *Texas v. United States*, the Supreme Court confronted an issue that was "contingent on a number of factors." 523 U.S. 296, 300 (1998). The Supreme Court found that "[u]nder these circumstances, where 'we have no idea whether or such [a sanction] will be ordered,' the issue [was] not fit for adjudication." *Id.* (quoting *Toilet Goods Assn., Inc. v. Gardner*, 387 U.S. 158, 163 (1967)) (second alteration in original). Likewise, in *Trump v. New York*, the Supreme Court found that "th[e] case [was] riddled with contingencies and speculation that impede judicial review" and that "[a]ny prediction how the Executive Branch might eventually implement this general statement of policy is 'no more than conjecture' at this time." 592 U.S. 125, 131 (2020). This case does not suffer from the same defects as those in *Texas* or *Trump*. The issues here are of sufficient immediacy—and have sufficiently crystallized—for the court's resolution. Indeed, in contrast to the cases cited by Lilly, FDA approval has no bearing on the substantive disputes between the parties—i.e., whether donanemab is a "Licensed Product" that incorporates "PDL Technical Information." Its relevance is limited to the accrual of damages since sales will not begin until donanemab is approved by the FDA.

In sum, PDL will suffer a concrete and particularized injury if Lilly does not pay royalties to PDL for donanemab as required by the Agreement. This injury is sufficiently actual or imminent in light of Lilly's representations that FDA approval is expected imminently.

III. CONCLUSION

For the foregoing reasons, PDL respectfully requests that the Court deny Lilly's motion to dismiss. PDL's complaint is factually sufficient—it contains sufficient factual allegations that, among other things, donanemab is a "Licensed Product" that "incorporates PDL Technical Information" under the Agreement. PDL's complaint is also legally sufficient—the factual allegations are sufficient to state the anticipatory breach of contract and declaratory judgment

claims contained therein. Finally, PDL has standing to sue Lilly since it will be injured once donanemab is approved by the FDA, an approval that is expected imminently.[5]

[5] Lilly requests that the Court "dismiss the complaint in its entirety with prejudice." ECF No. 36 at 3. Lilly provides no argument or legal basis for this extraordinary request. *See id.* Indeed, the phrase "with prejudice" is mentioned only once in the entire Motion. Regardless, to the extent the Court determines that dismissal is warranted, the Court should grant PDL an opportunity to amend its complaint. *Runnion v. Girl Scouts of Greater Chicago and Nw. Indiana*, 786 F.3d 510, 519 (7th Cir. 2015) ("a plaintiff whose original complaint has been dismissed under Rule 12(b)(6) should be given at least one opportunity to try to amend her complaint before the entire action is dismissed").

Dated: April 25, 2024

WILKINSON, GOELLER, MODESITT, WILKINSON & DRUMMY, LLP

/s/ Craig M. McKee

Craig M. McKee (Attorney No. 10245-82)
333 Ohio Street
Terre Haute, Indiana 47807
Tel: +1 812 232 4311
Fax: +1 812 235 5107
Email: cmmckee@wilkinsonlaw.com

OF COUNSEL:

David I. Gindler
Lauren N. Drake
ORRICK, HERRINGTON & SUTCLIFFE LLP
355 South Grand Avenue
Suite 2700
Los Angeles, CA 90071-1596
Tel: +1 213 629 2020
Fax: +1 213 612 2499
dgindler@orrick.com
ldrake@orrick.com

Carly Romanowicz
ORRICK, HERRINGTON & SUTCLIFFE LLP
222 Berkeley Street
Suite 2000
Boston, MA 02116
Tel: +1 617 880 1800
Fax: +1 617 880 1801
cromanowicz@orrick.com

Jordan B. Fernandes
ORRICK, HERRINGTON & SUTCLIFFE LLP
51 West 52nd Street
New York, NY 10019-6142
Tel: +1 212 506 5000
Fax: +1 212 506 5151
jfernandes@orrick.com

Jessica Stern
ORRICK, HERRINGTON & SUTCLIFFE LLP
405 Howard Street
San Francisco, CA 94105-2669
Tel: +1 415 773 5700
Fax: +1 415 773 5759
jstern@orrick.com